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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KIRAN K. CHADA, ROLAND CHOUINARD, HENA ASHAR
and ABU SAYED

Appeal 2009-013740
Application 10/768,566
Technology Center 1600

Decided: May 12, 2010

Before DONALD E. ADAMS, DEMETRA J. MILLS and
FRANCISCO C. PRATS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims 1, 8, 9, and 17-19, the only claims pending in this application. We have jurisdiction under 35 U.S.C. § 6(b).

STATEMENT OF THE CASE

The claims are directed to a method of reducing the amount of adipose tissue in a subject (claims 1, 8, and 9) and a method of reducing the level of adipose tissue formation in a subject (claims 17-19). Claims 1 and 17 are illustrative:

1. A method of reducing the amount of adipose tissue in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide compr[i]ses consecutive amino acids having the sequence set forth in SE[Q] ID NO: 1.

17. A method of reducing the level of adipose tissue formation in a subject comprising administering to the subject an amount of an sFRP-5 peptide effective to reduce the level of adipose tissue formation, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject, wherein the sFRP-5 peptide comprises consecutive amino acids having the sequence set forth in SE[Q] ID NO: 1.

The Examiner relies on the following evidence:

Xu	US 2003/0143610 A1	Jul. 31, 2003

The rejection presented by the Examiner follows:

Claims 1, 8, 9, and 17-19 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Xu.

We affirm.

ISSUE

Does Xu's method of administering Appellants' active agent in the Appellants' effective amount to the same patient population as Appellants inherently anticipate Appellants' claimed method?

FINDINGS OF FACT

FF 1. Xu teaches "a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO:2" (Xu 2: ¶ [0018]; 29: 12- 30: 10; Ans. 4).

FF 2. Appellants concede that Xu's SARP3 polypeptide having the amino acid sequence of SEQ ID NO: 2 is identical to Appellants' sFRP-5 polypeptide having the sequence of SEQ ID NO: 1 (App. Br. 13; *see also* Ans. 4).

FF 3. Xu teaches that "a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO:2 . . . or a fragment thereof" is a SARP3 modulator (Xu 2: ¶ [0018]; Ans. 4).

FF 4. Xu teaches "a method for treating a subject having a metabolic disorder characterized by aberrant SARP3 polypeptide activity or aberrant SARP3 nucleic acid expression, e.g., obesity, diabetes, anorexia, or cachexia", wherein "[t]he method includes administering to the subject a SARP3 modulator, e.g., in a pharmaceutically acceptable formulation" (*id.*).

FF 5. Appellants' Specification discloses that the invention "provides for an sFRP-5 polypeptide and methods of administration of such an sFRP-5 polypeptide to a subject for the treatment of obesity and other metabolic disorders related to an overabundance of adipose tissue" (Spec. 1: 16-18).

FF 6. Xu teaches that "a therapeutically effective amount of polypeptide (i.e., an effective dosage) ranges from about 0.001 to 30 mg/kg body weight" (Xu 15: ¶ [0133]).

FF 7. Appellants' therapeutically effective dosage is identical to Xu's. Specifically, Appellants' Specification discloses that "[a] therapeutically

effective amount of polypeptide (i.e., an effective dosage) ranges from about 0.001 to 30 mg/kg body weight" (Spec. 18: 27-28).

FF 8. Xu's

> [I]nvention is based, at least in part, on the discovery that the SARP3 (secreted apoptosis-related protein 3), also referred to herein as SFRP5 (secreted frizzled-related protein 5) nucleic acid and polypeptide molecules . . . are expressed at high levels in adipose tissue and hypothalamus, and are downregulated in leptin pathway deficient genetic animal models of obesity, but upregulated when fed a high fat diet. Without intending to be limited to any particular theory or mechanism of action, it is believed that SARP3 molecules can modulate lipid metabolism.

(Xu 2: ¶ [0020].)

FF 9. Xu teaches that in the ob/ob and db/bd "[g]enetic mouse models of obesity . . . mice showed a lower level of SARP3 expression as compared to their respective corresponding wild type strain, which is likely due to the absence of the leptin signaling pathway in these mice" (Xu 27: ¶ [0227]).

PRINCIPLES OF LAW

The test which determines whether an invention has been anticipated by a reference is whether the description of the invention in the reference is "sufficient to put the public in possession of the invention." *In re LeGrice*, 301 F.2d 929, 933 (1962); *In re Elsner*, 381 F.3d 1125, 1128 (Fed. Cir. 2004) (following *LeGrice*, and noting that "[i]n particular, one must be able to make the claimed invention without undue experimentation.").

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814

F.2d 628, 631 (Fed. Cir. 1987). Thus, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson,* 169 F.3d 743, 745 (Fed. Cir. 1999) (citations and internal quotation marks omitted).

Perricone v. Medicis Pharm. Corp., 432 F.3d 1368 (Fed. Cir. 2005) emphasizes this point by illustrating the difference between claims that recite a new use of an old composition and claims that recite a newly recognized benefit of an old method. *Perricone* involved two sets of claims, one directed to preventing sunburn damage and the other to treatment of skin sunburn. In each case, the claims required topical application of a fatty acid ester of ascorbic acid. The prior art described topical application of the same compound (among thirteen others) to skin, in an amount that encompassed the claimed effective amount. The *Perricone* court found that the claims directed to preventing sunburn damage to exposed skin surfaces were anticipated by the prior art, even though the prior art "[did] not disclose any benefit directed to skin sunburn, or any of the other specific skin disorders, as claimed" (*id.* at 1376). On the other hand, the court found that the claims directed to treating skin sunburn were directed to a new use of the prior art compounds, and therefore not anticipated, because the prior art "[did] not disclose topical application to skin sunburn" (*id.* at 1379). That is, the prior art did not disclose applying the compound to the same population (people with sunburn) as required by the claims. As the court explained, "[t]he issue

is not . . . whether [the prior art] lotion *if applied* to skin sunburn would inherently treat that damage, but whether [the prior art] discloses the application of its composition to skin sunburn" (*id.* at 1378).

Arguments not made are waived. *See* 37 C.F.R. § 41.37(c)(1)(vii).

ANALYSIS

Appellants contend that "claims 1, 8, 9 and 17-19 do not stand together but stand separately" (App. Br. 11). Appellants, however, provide separate arguments for the following groups of claims: (I) claims 1, 8, and 9 and (II) claims 17-19 (*see* App. Br. 14 and 16). Accordingly, we have reviewed the record as it relates to representative claims 1 and 17. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 1:

Claim 1 is drawn to a method of reducing the amount of adipose tissue in a subject. The claimed method comprises administering to a subject an amount of a sFRP-5 peptide effective to reduce the amount of adipose tissue, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject. Claim 1 defines the sFRP-5 peptide as a peptide comprising consecutive amino acids having the sequence set forth in SEQ ID NO: 1.

Both Appellants and Xu teach the treatment of the same patient population, e.g., an obese subject (FF 4 and 5), with an identical dosage (FF 6 and 7) of an identical active agent (FF 2 and 3). Accordingly, we find no error in the Examiner's finding that while Xu does not teach the reduction of adipose tissue, since Xu administers the identical dosage of an identical

active agent to the same patient population as Appellants, Xu's method will inherently reduce the amount of adipose tissue in a subject (*see* Ans. 4).

Since Xu teaches the same dosage as disclosed by Appellants (FF 6 and 7) we are not persuaded by Appellants' contentions with regard to dosage (Reply Br. 9-10).

Appellants contend that Xu fails to teach the administration of "(i) an amount of an sFRP-5 peptide effective to reduce the amount of adipose tissue, or (ii) an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject" (App. Br. 13). We are not persuaded.

Claim 1 requires that the sFRP-5 peptide either reduce the amount of adipose tissue *or* stimulate expression of the sFRP-5 peptide in the subject. Since Xu administers the identical dosage of an identical active agent to the same patient population as Appellants, Xu's method will inherently reduce the amount of adipose tissue in a subject. Thus, Xu anticipates claim 1. Accordingly, we do not reach the merits of the alternative embodiment of claim 1 regarding the amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject.

We are not persuaded by Appellants' contention that Xu fails to teach "what the 'modulator should do[']" or "what 'modulating' SARP3 means" (App. Br. 14). The mechanism of action through which an active agent acts is not at issue. To the contrary, the question is whether Xu's method reduces the amount of adipose tissue in a subject, by administering the same active agent, in the same dosage, to the same patient population. We find no persuasive argument or evidence on this record to support a conclusion that Xu's method would not inherently reduce the amount of adipose tissue in a subject.

Appellants contend that the Examiner mischaracterized Xu's teaching because a portion of Xu identifies "at least sixteen different possible types of 'modulators,' including 'modulators' that clearly achieve different ends" (Reply Br. 7; *see generally* Reply Br. 6-9). We are not persuaded. Xu teaches that SARP3 expression levels are down regulated in leptin pathway deficient genetic animal models of obesity (FF 8 and 9) and teaches that obesity can be treated by administering an effective amount of a SARP3 polypeptide comprising the amino acid sequence of SEQ ID NO: 2 (FF 3).

For the foregoing reasons we are not persuaded by Appellants' contention that Xu "does not teach anything which could inherently result in the claimed invention" (App. Br. 16). For the same reasons we are not persuaded by Appellants' contention that *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368 (Fed. Cir. 2005) supports a different conclusion (App. Br. 17). The *Perricone* court found that claims directed to preventing sunburn damage to exposed skin surfaces were anticipated by the prior art, even though the prior art "[did] not disclose any benefit directed to skin sunburn, or any of the other specific skin disorders, as claimed" (*id.* at 1376). By analogy, Xu administers the identical dosage of an identical active agent to the same patient population as Appellants, thus, Xu's method will inherently reduce the amount of adipose tissue in a subject.

Lastly, for the reasons set forth by the Examiner (Ans. 9), we are not persuaded by Appellants' contention that Xu fails to provide an enabling disclosure of Appellants' claimed invention because the Examiner of Xu rejected Xu's invention as lacking an enabling disclosure (App. Br. 19; Reply Br. 10-12).

Claims 17-19:

Claim 17 is drawn to a method of reducing the level of adipose tissue formation in a subject. The claimed method comprising administering to the subject an amount of a sFRP-5 peptide effective to reduce the level of adipose tissue formation, or an amount of a molecule effective to stimulate expression of the sFRP-5 peptide in the subject. Claim 17 defines the sFRP-5 peptide as a peptide comprising consecutive amino acids having the sequence set forth in SEQ ID NO: 1.

Appellants separate argument of claims 17-19 are a corollary to the contentions made with regard to claim 1 (*see* App. Br. 14 and 16). We are not persuaded for the reasons set forth above. In sum, since Xu administers the identical dosage of an identical active agent to the same patient population as Appellants, Xu's method will inherently reduce the level of adipose tissue formation in a subject.

CONCLUSION OF LAW

Xu's method of administering Appellants' active agent in Appellants' effective amount to the same patient population as Appellants inherently anticipates Appellants' claimed method.

The rejection of claims 1 and 17 under 35 U.S.C. § 102(e) as being anticipated by Xu is affirmed. Claims 8 and 9 fall together with claim 1. Claims 18 and 19 fall together with claim 17.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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